Remarks

The subject invention pertains to the fabrication of microfluidics devices having fluid passages in an elastomeric portion thereof, mounted on a rigid substrate, and having a fluid supply and/or other interconnects, e.g. fiber optic cables, electrical conductors, etc., attached thereto, by means of encapsulating the device in a curable resin which exhibits volumetric shrinkage upon cure, thus securing the elastomeric body to the rigid substrate and fixing the various interconnects in place, forming a robust assembly.

Claims 10 - 19 have been rejected under 35 U.S.C. § 102(b) as "anticipated by admitted prior art."[1] Applicants respectfully traverse this rejection. In the process of manufacturing Applicants' devices, the volumetric contraction of the thermosetting resin produces a stress on the various components of the structure, pressing them together. For example, a microfluidic channel in Figure 1 is contained within the soft elastomer PDMS body 5, and for the device to operate, must form a closed channel by adjoining the surface 2 of substrate 3 in a non-leaking manner.

Prior to Applicants' invention, such devices were produced by bonding the elastomer to a glass substrate in an oven, so-called "baking". As a result, the elastomer is chemically bonded to the glass, but outgassing of volatiles may occur in the process.

In Applicants' process, the baking and chemical bonding which results therefrom is replaced by simple pressure, pressure generated by contraction of the curable resin during its cure. The Applicants' specification does not teach or suggest embedding <u>any</u> device within a curable resin, much less a curable resin which contracts upon cure. Thus, the

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[1] Applicants have "admitted" no prior art. Applicants disclosure on pages 1 - 3 "related art," not "prior art." The burden is on the Office to show that each element the Office relies on is "prior art," e.g. under one of the prior art categories of 35 U.S.C. § 102. Applicants indicated in their last response (page 5) that the descriptive material on pages 1 - 3 is <u>not</u> admitted to be prior art, with the exception of Figures 1 and 2, which are labeled "Prior Art".

rejection over Applicants' own specification under 35 U.S.C. § 102(b) must be withdrawn for this reason alone.

However, in addition, the devices prepared by chemical bonding of the elastomer to the substrate by baking, are different from those wherein the elastomer is pressed against the substrate by pressure generated by a contracting resin as it cures. In Applicants claimed devices, there is no chemical bond between the substrate and the elastomers; only a pressure seal is established during manufacture by the pressure generated by resin contraction. Thus, the devices are different from those of the prior art in this respect also, and thus the rejection under 35 U.S.C. § 102(b) must be withdrawn for this reason as well. It is axiomatic in patent law that when a product made by a process is in fact different from a product produced by other processes, that the product is indeed patentable. Here, the prior art products' elastomer bodies were chemically bonded to the substrate, whereas the presently claimed devices are not manufactured with a chemical bond. Thus, the products are different.

Claims 1 - 9 and 20 have been rejected under 35 U.S.C. § 103(a) over Applicants' "admitted prior art", (which, as Applicants have indicated previously, is not "admitted."), in view of Bauer U.S. Patent 4,304,749 ("*Bauer*"). Applicants respectfully traverse this rejection, and respectfully request that the Office cite patents and publications or an Affidavit under 37 C.F.R. § 1.04 in support of its interpretation of the *Bauer* reference, if this rejection is maintained. Applicants traverse the rejection for numerous reasons.

First, *Bauer* is not in the same filed of endeavor as Applicants' devices. The Examiner contends, without any support, that fluidics and microfluidics are in the same field, essentially, as Applicants understand it, because both words include the letters "fluidics." This is incorrect. Fluidics devices such as those of *Bauer* (oscillating or vibrating spray heads) which involve large scale (high volume) flow of fluids at considerable pressure, are far removed from "microfluidics" devices, which, as known by the skilled artisan, involve channels and reservoirs of μm and nm dimensions, fluid flows from low nanoliter to microliter amounts, and pressures which are close to ambient. One skilled in the art of microfluidic

devices would not look to a patent directed to high volume, pressurized spray heads for a solution to any problem in microfluidics.

Second, *Bauer* is not directed to the problem solved by Applicants: sealing of interconnects within an elastomeric microfluidics body and sealing open channels within that elastomeric body to a rigid substrate. Applicants have carefully perused *Bauer*, and fail to find any mention of any elastomer, any interconnects inserted into the elastomer, or any discussion of pressuring an elastomer against a rigid substrate. Since *Bauer* is neither in the same field of endeavor as Applicants, nor is it directed to any problem solved by Applicants, it is not analogous art under the standards set by multitudinous legal precedent, *In re Clay*, 966 F.2d 656, 659 (Fed. Cir. 1992); *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d, 443, 449 (Fed. Cir. 1986); *In re GPAC, Inc.*, 57 F.3d 1574, 1578 (Fed. Cir. 1995). If the Office continues to assert that *Bauer* is analogous art, it must cite a reference which supports such a belief, and not merely conclude that because both references involve fluids that the *Bauer* reference is analogous.

Second, there is no evidence of any motivation to combine these references. Motivation to combine must be proven independently of whether or not a reference is or is not analogous. Applicants' invention is directed to a low cost and efficient method of manufacturing microfluidics devices which contain microchannels which must remain open and unobscured in order for such devices to function. *Bauer* is directed to sealing by injection molding thermoplastic material under pressure around a vibrating spray head device. One skilled in microfluidics device technology would not be tempted to use injection molding of thermoplastics to encapsulate such fragile devices, as the high pressures encountered would be expected to cause compaction of the elastomer, thus altering the geometry of the extremely small channels.

The Office has not provided any evidence supporting the combination of *Bauer* with Applicants' disclosure. The Federal Circuit has addressed this issue on numerous occasions, including *In re Lee*, 277 F.3d. 1338, 1343-44 (Fed. Cir. 2002) where the Court

expressed skepticism about invoking the ubiquitous "knowledge of the skilled artisan" by the Office to supply motivation to combine. The Federal Circuit stated clearly that motivation must be established by more than "subjective belief and unknown authority." *See* also *Princeton Biochemicals, Inc., v. Beckman Coulter, Inc.;* Slip Opinion, June 9, 2005, Case 04-1493 (Federal Circuit), page 11. Here, there is no motivation to combine except the Office's unsupported statement that "one of ordinary skill in the art [of microfluidic devices][2] would look to *Bauer*". This is exactly the same unsupported "subjective belief and unknown authority" which the Federal Circuit has stated cannot satisfy the legal requirements for combination. If *Bauer* is to be combined with Applicants' disclosure, a reference must be cited which provides the motivation to combine, or an Affidavit from one skilled in the art of microfluidic devices. In the absence of this or other actual evidence, the combination is not legally proper. *See In re Dembiczak*, 50 U.S.P.Q.2d 1614 (Fed. Cir. 1999); (requirement for showing the teaching or motivation to combine references is "rigorous," and must be "clear and particular.") *See* also, *C.R. Bard v. M3 Sys., Inc.*, 48 U.S.P.Q.2d 1225, 1232 (Fed. Cir. 1998) (merely because references can be combined, the mere suitability for logical combination does not provide motivation for the combination); *See* also, *McElmurry v. Arkansas Power & Light Co.*, 27 U.S.P.Q.2d 1129, 1131 (Fed. Cir. 1993) (mere conclusory statements supporting the proposed combination, standing alone are not "evidence").

Finally and most importantly, even were the combination proper, it does not teach or suggest the claimed invention. The claimed invention requires, in addition to positioning an elastomer portion onto a rigid substrate and at least one interconnect, embedding the device in a curable resin which exhibits volumetric contraction upon curing, and curing the resin. Encapsulating a microfluidics device with any resin, curable or not, is not shown by the portion of Applicants' specification discussing the related art, nor by Figures 1 or 2, nor by *Bauer*. If the Office disagrees, it is invited to point with particularity to those portions of *Bauer*, or those portions of Applicants' specification where a "prior art" encapsulation of a microfluidics device is disclosed.

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[2] The Office does not include "of microfluidic devices" in its "motivational conclusion". However, this is the art to which the invention pertains.

Also, *Bauer* does not disclose use of any curable resin. *Bauer* discloses only the injection molding of thermoplastic resin around his prefabricated fluidic element. As is so well known as to require judicial notice thereof, thermoplastic resins which solidify after injection molding in a molten state are not "curable resins" since they do not cure, but only change physical state. A "curable resin" is known by those skilled in the art to refer to resins which cure by chemical reaction, i.e. are crosslinkable or chain-extendable resins, commonly called "thermoset" resins. Examples in common use include epoxy resins which cure through the chemical reaction of the oxirane (epoxy) group with other groups reactive therewith. Further examples are polyurethane resins used in reaction injection molding (RIM) in the automobile industry, which cure by both crosslinking and chain extension caused by reaction of a di- or polyisocyanate with polyhydroxyl and polyamino compounds. "Curable resin" as used in the claims is synonymous with "thermosetting resins" or "thermoset resins" and like terms used by those skilled in the art of curable resins. To Applicants' knowledge, the solidification of thermoplastics has never been referred to as "curable" or "curing", since no chemical reaction ("curing") is involved. If the Office is to continue to assert otherwise, it must supply a reference in support of its position.

On page 3 of the Office Action, it is stated:

> The added secondary reference teaches as conventional the feature of forming a fluidic structure using a polymeric material that does not require baking, having contracting properties as claimed. A cover 23 and substrate 23 are provided adjacent one another such that there is provided a fluid passage therebetween. A thermoset plastic resin is injected into the mold cavity to encapsulate the assembly, such that it contracts upon solidification. *See,* col. 5, lines 1 - 15. (emphasis added).

This statement by the Office is incorrect, as *Bauer*, the secondary reference, does not disclose, teach, or suggest injecting a thermoset resin into a mold cavity. At the relevant passages, *Bauer* states:

> When plastic is injected into opening 84 it flows through and fills channels 81 and holes 78 and 79. Upon solidifying the plastic in the holes applies a shrinkage stress compression force which holds the body member and cover plate together. (emphasis added).

and further:

> As briefly mentioned above, the parts to be assembled are preferably made of a thermo-set plastic such as a phenolic. The injected plastic material could then be any other injection moldable plastic. Alternatively, polypropylene or certain acetal plastics can be used for the assembled members and the same material or ABS (having a slightly lower melting temperature) can be injected as the sealer. In this regard it should be noted that the injected material comprises far less mass than the assembled parts so that "cold-shot" injection may be used wherein the injected material cools before the base materials melt. (emphasis added).

Thus, the term "thermoset" refers to the "parts to be assembled", around which a "injected plastic material" is injected into the mold cavity. The thermoset parts have already been formed, and it is these that are desired to be sealed. It is clear that the material injected to seal the parts is a thermoplastic which shrinks as it changes phase (solidifies; col. 3, line 19; column 2, lines 42 - 43; column 5, lines 3 - 4). Thus, *Bauer* does not disclose injecting any thermosetting (curable) resin. If the Office disagrees, the Office is invited to point with particularity to those portions of *Bauer* which unambiguously disclose injecting a curable resin, mindful that the law requires that any ambiguity on the part of any reference be resolved in favor of the Applicant, *In re Sheppard*, 144 USPQ 42 (CCPA 1964), which is binding

precedent in this regard. For all these reasons, withdrawal of the rejection of claims 1 - 9 and 20 is solicited.

With respect to claims 6 and 7 in particular, no prior art description of these resins is seen. For example, there is no mention of epoxy resin in *Bauer*, and the only thermoset resins disclosed by *Bauer* for formation of his initial internal parts, phenolic resins, are not the equivalent of the claimed epoxy resins which also decrease volumetrically upon cure. Factually, there is no evidence that any phenolic resins exhibit any volume contraction. The unsupported statement that the resins of claims 6 and 7 are "equivalent" is without support. If this rejection is maintained, the Office must provide evidence that phenolic resins, the only thermoset resins disclosed by *Bauer* (for a different purpose, however), are resins which exhibit volume contraction upon cure. The rejection of claims 6 and 7 must be withdrawn on this basis as well.

With respect to claims 8 and 20, *Bauer* does not disclose a cavity in a frame, nor would such work in *Bauer's* process, since one cannot injection mold into a frame, only into a closed cavity. For claim 20, the thermoplastics of *Bauer* are not taught to be poured, nor could they be as thermoplastic resins for injection molding are to viscous at their melting points for this to be practical. High pressure screw extruders are used for injection molding. These claims are separately patentable.

In all fairness to Applicants, the prior art does not disclose, teach, or suggest the claimed process, whether alone or in any combination. Applicants have discovered a low cost solution to fabrication of delicate microfluidics devices which allows production of a robust device without the drawbacks associated with prior art methods of chemically bonding elastomer to glass. The prior art does not teach or suggest this elegant result.

Applicants submit that the claims are now in condition for Allowance, and respectfully request a Notice to that effect. If the Examiner believes that further discussion will advance the prosecution of the Application, the Examiner is highly encouraged to telephone Applicants' attorney at the number given below.

Respectfully submitted,

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